IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9339

Bartle, J. August 14, 2014

Carol J. Meyer ("Ms. Meyer" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period.[3] See Settlement Agreement §§ IV.B.1.a. & I.22.

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2. (...continued)
not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See Settlement Agreement § I.49.

In April, 2012, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C., F.A.H.A. Based on an echocardiogram dated March 30, 1998, Dr. Dlabal attested in Part II of claimant's Green Form that Ms. Meyer had mild aortic regurgitation, congenital aortic valve abnormalities,[4] surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™, New York Heart Association Functional Class III symptoms, and a left ventricular ejection fraction < 40% at any time six months or later after the valvular repair or replacement surgery.[5] Based on such findings, claimant would be entitled to Matrix B-1, Level V benefits in the amount of $244,990.[6]

In the report of claimant's March 30, 1998 echocardiogram, the reviewing cardiologist, Steven A. Schwartz,

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4. The presence of congenital aortic valve abnormalities requires the payment of reduced Matrix Benefits for a claim based on damage to the aortic valve. See Settlement Agreement § IV.B.2.d.(2)(c)i)a).

5. Dr. Dlabal also attested that claimant suffered from arrhythmias and a reduced ejection fraction in the range of 50% to 60%. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she qualifies for payment at Matrix Levels III or IV, has New York Heart Association Functional Class III or Class IV symptoms, underwent surgery to repair or replace the aortic and/or mitral valve(s), and had a left ventricular ejection fraction of less than 40% six months or later after valvular repair or replacement surgery. See Settlement Agreement § IV.B.2.c.(5)(b)ii).

M.D., observed that Ms. Meyer had "calcific aortic valve disease with probably only mild stenosis." Dr. Schwartz, however, did not state that Ms. Meyer had mild or greater aortic regurgitation, and he did not specify a percentage as to the level of claimant's aortic regurgitation. Under the definition set forth in the Settlement Agreement, mild or greater aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable) is equal to or greater than ten percent (10%) of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement § I.22.

In May, 2012, the Trust forwarded the claim for review by Waleed N. Irani, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Irani determined that there was a reasonable medical basis for the attesting physician's representation that Ms. Meyer had mild aortic regurgitation. Pursuant to Court Approved Procedure ("CAP") No. 11, the Consensus Expert Panel[7] subsequently reviewed the claim and determined that it should be re-audited because the "Group finds no [reasonable medical basis] for mild aortic regurgitation based

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7. The Consensus Expert Panel consists of three cardiologists, one designated by each of Class Counsel, the Trust, and Wyeth. See Pretrial Order ("PTO") No. 6100 (Mar. 31, 2005). We approved creation of the Consensus Expert Panel to "monitor the performance of the Auditing Cardiologists and to develop procedures for quality assurance in the Audit of Claims for Matrix Compensation Benefits." Id.

on review of multiple echocardiograms." In August, 2012, the Trust informed Ms. Meyer that it had accepted the Consensus Expert Panel's recommendation that her claim be re-audited.

Thereafter, the Trust forwarded the claim for review by another auditing cardiologist, Irmina Gradus-Pizlo, M.D., F.A.C.C., F.A.S.E. In audit, Dr. Gradus-Pizlo concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Specifically, Dr. Gradus-Pizlo stated:

> No evidence of aortic regurgitation in multiple views: [long-axis], 4 chamber, 3 chamber by color Doppler (even with Nyquist at 47) or by spectral doppler.
>
> Also no evidence of aortic regurgitation on the follow up [echocardiogram] [dated] 8/26/98.
>
> I agree with the original report [of] 3/30/98 which states that there is mild aortic stenosis, no regurgitation described.

Based on Dr. Gradus-Pizlo's determination that Ms. Meyer did not have at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Program, the Trust issued a post-audit determination denying Ms. Meyer's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this

adverse determination.[8] In contest, Ms. Meyer argued that it is not the role of the auditing cardiologist to "second guess" the attesting physician and that deference is to be given to the attesting physician.[9] In addition, claimant asserted that there was a reasonable medical basis for her claim because four cardiologists, including one of the Trust's auditing cardiologists, agreed that the March 30, 1998 echocardiogram demonstrated at least mild aortic regurgitation. In support, claimant submitted declarations from Dr. Dlabal and Gerald M. Koppes, M.D. In his declaration, Dr. Dlabal stated, in pertinent part:

> 2. I reviewed the CD containing Carol J. Meyer's echocardiographic studies dated 3/30/1998, 8/26/1998, 4/15/1999, and 1/17/2000. I reviewed the full echocardiographic studies, including all loops and frames.
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> 3. Contrary to Dr. Gradus-Pizlo's statement that there was "no evidence of [aortic insufficiency] in multiple views: [long-axis], 4 chamber, 3 chamber by

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8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Meyer's claim.

9. Claimant also contested the auditing cardiologist's finding that there was a reasonable medical basis for the attesting physician's finding that claimant had a congenital aortic valve abnormality. Given our disposition with respect to claimant's level of aortic regurgitation, we need not address this issue.

> color Doppler or by spectral Doppler," I found mild [aortic insufficiency] on all four (4) of these studies....
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> 4. Based on my visual assessment mild [aortic insufficiency] was present; the JH/LVOTH ratio varied from 10% to 40%....
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> 5. Given that several of the images show a volume of color with aliasing in diastole at a level below the [aortic valve], it is reasonable to conclude that there was at least mild [aortic insufficiency].
>
> 6. These regurgitant jets were true regurgitant jets, and they were representative of other jets that were also in the mild range.
>
> 7. In my opinion, there was a reasonable medical basis for a finding of mild [aortic insufficiency] in this case.[10]

In his declaration, Dr. Koppes also asserted that claimant's March 30, 1998 echocardiogram, as well as claimant's April 15, 1999 and January 17, 2000 echocardiograms, demonstrated at least mild aortic regurgitation, stating, "Mild [aortic insufficiency] was present based on my visual assessment as well as by my own measurements. A JH/LVOTH ratio of 15%, clearly exceeded 10%. The jets were true regurgitant jets, and they were representative of other jets that were also in the mild range."

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10. Dr. Dlabal also attached still frame images from claimant's echocardiogram, which purportedly demonstrated at least mild aortic regurgitation.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Gradus-Pizlo submitted a declaration in which she again concluded that there was no reasonable medical basis for Dr. Dlabal's representation that Ms. Meyer had at least mild aortic regurgitation. Dr. Gradus-Pizlo explained, in pertinent part:

> 11. With respect to the March 30, 1998 study, I reviewed the entirety of the study as well as those specific points identified by Drs. Koppes [sic]. I found no aortic regurgitation at the specific points identified by Dr. Koppes as demonstrating mild aortic regurgitation: At 1:05-1:11, I found no evidence of aortic regurgitation; at 4:38-4:47, what is seen is clearly mitral inflow, not aortic regurgitation.
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> 12. With respect to the March 30, 1998 study, I reviewed the entirety of the study as well as those specific points identified by Dr. Dlabal. I did not find aortic regurgitation at 2:44:22, where Dr. Dlabal states that mild aortic regurgitation is seen. The "red splotch" that he identifies is not aortic regurgitation. It is neither continuous nor seen over several frames. Aortic regurgitation is a continuous, several frame event that takes up over half of a cardiac cycle, and cannot be diagnosed based upon a single frame. In this particular study, the Claimant's heartbeat is slow, at 62 beats per minute. If aortic regurgitation were present, there would be plenty of time to observe it on this study, however there is no aortic regurgitation.

13. With respect to the August 26, 1998 study, I reviewed the entirety of the study as well as those specific points identified by Dr. Dlabal. I found no aortic regurgitation at the specific points identified by Dr. Dlabal as demonstrating mild aortic regurgitation: Frames 7:44:21 and 22-25 do not show any aortic regurgitation, and in fact include systolic frames; frames 7:46:22-28 (which are in the 3 - not 2 - chamber view) show mitral inflow, not aortic regurgitation. The "splashes" of color identified by Dr. Dlabal are not aortic regurgitation, for the reasons I noted above - aortic regurgitation is a continuous process, and does not manifest as "splotches" or "splashes" of color.

14. With respect to the April 15, 1999 study, I reviewed the entirety of the study as well as those specific points identified by Drs. Koppes and Dlabal. I found no aortic regurgitation at the specific points identified by Dr. Koppes as demonstrating mild aortic regurgitation: Frames 2:06-2:14 occur during the systolic cycle, and do not demonstrate aortic regurgitation; the frames at 4:10-4:18 are not in color. Nor did I find aortic regurgitation at the points identified by Dr. Dlabal as demonstrating "splashes of aliased color" representing mild aortic regurgitation.

15. With respect to the January 17, 2000 study, I reviewed the entirety of the study as well as those specific points identified by Drs. Koppes and Dlabal. I found no aortic regurgitation at the specific points identified by either.

16. All of these studies are thorough and of good quality. Starting on the 4/15/99 study, the studies include thorough interrogation of the [left ventricular] outflow tract. There is no aortic regurgitation seen on any of these

> studies, a conclusion that is supported by the echocardiogram reports.

The Trust then issued a final post-audit determination, again denying Ms. Meyer's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On March 12, 2013, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 9025 (Mar. 12, 2013).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 12, 2013, and claimant submitted a sur-reply on July 9, 2013. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[11] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See

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11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for finding that Ms. Meyer suffered from at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Meyer reasserts the arguments she made during contest. Claimant further asserts that her physicians adequately rebutted the findings of the auditing cardiologist and established a reasonable medical basis for a finding of at least mild aortic regurgitation. Ms. Meyer

contends that the auditing cardiologist failed to provide any details in her opinions and, as such, there is no evidence that her findings are representative of the entire echocardiogram study. Claimant also submitted a supplemental declaration from Dr. Dlabal, in which he again opines that the auditing cardiologist is incorrect and that claimant's March 30, 1998 echocardiogram reveals the presence of at least mild aortic regurgitation. Dr. Dlabal stated, in pertinent part:

> Taken singly and in combination, each and every echocardiogram through 2000 showed at least mild [aortic insufficiency]. The presence of at least mild [aortic insufficiency] on all studies was significant, consistent, and diagnostic in itself. Were the jets artifact, they would have appeared only sporadically, inconsistently as to character, and certainly not on every study.

Finally, claimant asserts that the Settlement Agreement and the Seventh Amendment to the Settlement Agreement "guaranteed class members certain benefits related to valve surgery and its aftermath."

In response, the Trust argues that claimant has not established a reasonable medical basis for Dr. Dlabal's representation that claimant had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. In addition, the Trust contends that the findings of the attesting physician are not entitled to deference and that the auditing cardiologist and the Trust

properly applied the reasonable medical basis standard. The Trust also asserts that the auditing cardiologist specifically states that there was no aortic regurgitation so that there would be no measurements or times to identify. Finally, the Trust also notes that the Settlement Agreement does not "guarantee" claimants high-level Matrix Benefits.

The Technical Advisor, Dr. Vigilante, reviewed all of claimant's echocardiograms and concluded that there was no reasonable medical basis for finding that Ms. Meyer had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. As to claimant's March 30, 1998 echocardiogram, Dr. Vigilante explained, in pertinent part:

> There were several cardiac cycles in the parasternal long-axis view in which the color flow was best evaluated. I digitized these cardiac cycles and used electronic calipers to the [sic] measure the JH and LVOTH. There were only two cardiac cycles in which aortic regurgitation was seen in the parasternal long-axis view. This was a very thin jet seen immediately below the aortic valve and not traveling more than 1 cm below the aortic valve. The JH was no more than 0.10 cm in diameter. The LVOTH was 2.20 cm in diameter. Therefore, the largest representative JH/LVOTH ratio was 5% diagnostic of trace aortic regurgitation.[12] Flow in the left

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12. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace, trivial, or physiologic mitral regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or <+ 5%

(continued...)

> ventricular outflow tract and through the aortic valve was also noted in the apical views. In this view, no aortic regurgitation was seen. I paid particular attention to the time frames documented by Dr. Koppes and Dr. Dlabal. Only trace aortic regurgitation was seen at counter 2:44:22. No aortic regurgitation was seen in any of the apical time frames documented by Dr. Dlabal. In these time frames, only left ventricular inflow was present.
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> As to claimant's August 26, 1998 echocardiogram,

Dr. Vigilante stated, in pertinent part:

> The parasternal long-axis view was available for the evaluation of aortic regurgitation. I digitized the cardiac cycles in the parasternal long-axis view in which color flow could be evaluated. I then determined the JH and LVOTH with electronic calipers. The largest representative JH was 0.15 cm. This was a very thin and small jet noted only immediately below the aortic valve and did not travel more than 1 cm in the left ventricular outflow tract. The LVOTH was 2.2 cm. Therefore, the largest representative JH/LVOTH ratio was 7% diagnostic of trace aortic insufficiency. Close evaluation of non-qualifying apical views failed to demonstrate aortic regurgitation on color flow Doppler. I paid close attention to the time frames documented by Dr. Dlabal. There was no evidence of aortic regurgitation in these non-qualifying apical views. Only left ventricular inflow was present.
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> As to claimant's April 15, 1999 echocardiogram,

Dr. Vigilante explained, in pertinent part:

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12. (...continued)
RJA/LAA."

> The parasternal long-axis view was available for the evaluation of aortic regurgitation. All cardiac cycles in which color flow Doppler was performed in the parasternal long-axis view were digitized. There was no evidence of aortic regurgitation in the parasternal long-axis view even evaluating this in a frame-by-frame method. Therefore, there was no JH. The LVOTH was 2.2 cm. In addition, close evaluation occurred in the apical views. There was no aortic regurgitation seen in the apical views. Close attention was given to the time frames documented by Dr. Koppes and Dr. Dlabal in their Declarations. However, only left ventricular inflow was seen. There was no evidence of aortic regurgitation.
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> Finally, as to claimant's January 17, 2000

echocardiogram, Dr. Vigilante determined, in pertinent part:

> This was an incomplete study. There was no color flow Doppler performed in the parasternal long-axis view. Therefore, this view was not available for the evaluation of aortic regurgitation. The Nyquist limit was appropriately set at 59 cm per second at a depth of 16 cm in the parasternal short-axis view and at 61 cm per second at a depth of 17 cm in the apical views.
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> .... The apical views were evaluated for the presence of aortic regurgitation. All cardiac cycles were digitized during color flow determination in the apical three and five chamber views. There was no evidence of aortic regurgitation in a frame-by-frame evaluation of these cardiac cycles. Close attention was given to the time frames mentioned in the Declarations of Dr. Koppes and Dr. Dlabal. The time frames documented by Dr. Dlabal demonstrated left ventricular inflow and not aortic regurgitation.
>
> Based on the entirety of his review, Dr. Vigilante

concluded:

> ... [T]here is no reasonable medical basis for a finding of mild or greater aortic regurgitation based on Claimant's March 30, 1998 echocardiogram, Claimant's August 26, 1998 echocardiogram, Claimant's April 15, 1999 echocardiogram or Claimant's January 17, 2000 echocardiogram. That is, none of these studies demonstrate aortic regurgitation worse than trace with comments as above. An echocardiographer could not reasonably conclude that greater than trace aortic regurgitation was present on any of these studies even taking into account the issue of inter-reader variability.

In response to the Technical Advisor Report,[13] claimant argues that the Technical Advisor failed to apply the reasonable medical basis standard because he "found that there was **not one** reasonable medical basis for the Attesting Physician's finding of mild aortic insufficiency (AI)." In addition, claimant submits that we should not accept Dr. Vigilante's opinion because Dr. Vigilante did not dispute the findings of Dr. Dlabal and/or Dr. Koppes as to claimant's March 30, 1998 and April 15, 1999

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13. Claimant initially included verified "rebuttal" by Dr. Dlabal with her response to the Technical Advisor Report. Pursuant to Audit Rule 34, the Special Master determined this rebuttal could not become part of the Show Cause Record. Thereafter, claimant filed "objections" to the decision denying the inclusion of this rebuttal in the Show Cause Record and a motion to have it included. According to claimant, in his rebuttal, Dr. Dlabal disputed the Technical Advisor's finding of at most trace aortic regurgitation. Pursuant to Audit Rule 34, there is no procedure by which Dr. Dlabal's supplemental statements can become part of the Show Cause Record. See, e.g., Mem. in Supp. of PTO No. 9041, at 9 n.11 (Apr. 5, 2013); Mem. in Supp. of PTO No. 8402, at 12 n.13 (Feb. 22, 2010). For these reasons, we will overrule claimant's objections and deny her motion.

echocardiograms and Dr. Vigilante falsely claimed only to see left ventricular inflow during the times identified by Dr. Dlabal as to claimant's April 15, 1999 and January 17, 2000 echocardiograms.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. In particular, we do not agree with claimant that the declarations of Dr. Dlabal and Dr. Koppes support a finding that Ms. Meyer's echocardiograms demonstrated at least mild aortic regurgitation.[14] Although Dr. Dlabal and Dr. Koppes identify a number of frames on claimant's echocardiogram that they contend demonstrate at least mild mitral regurgitation, Dr. Gradus-Pizlo reviewed claimant's echocardiograms, including these specific instances of purported mild aortic regurgitation, and determined that the echocardiograms did not support the findings of Dr. Dlabal and Dr. Koppes. Specifically, Dr. Gradus-Pizlo identified the supposed regurgitation identified by claimant's experts as left ventricular inflow rather than aortic regurgitation.

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14. We also do not agree that there is a reasonable medical basis for Ms. Meyer's claim simply because Dr. Irani opined that there was a reasonable medical basis for finding mild aortic regurgitation on claimant's March 30, 1998 echocardiogram. As previously stated, the Consensus Expert Panel reviewed the echocardiogram and recommended that the claim be reaudited because the group did not believe there was a reasonable medical basis for the finding.

Claimant subsequently submitted a second declaration of Dr. Dlabal wherein he disputed that the purported regurgitation was inflow. According to Dr. Dlabal, the flow identified was diastolic, continuous, and separate from the mitral inflow. Dr. Vigilante, however, reviewed claimant's echocardiograms and determined that Ms. Meyer's echocardiograms demonstrated at most trace aortic regurgitation.[15] Dr. Vigilante also confirmed that "only left ventricular inflow was seen" during the times identified by Dr. Dlabal and Dr. Koppes as supposed regurgitation.[16] Such an unacceptable practice cannot provide a reasonable medical basis for the resulting diagnosis of mild aortic regurgitation. To conclude otherwise would allow Diet Drug Recipients who do not have mild or greater aortic regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.

Finally, we do not agree that claimant is entitled to Matrix Benefits under the Seventh Amendment. As an initial

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15. For these reasons as well, we reject claimant's assertion that the auditing cardiologist and the Technical Advisor did not properly apply the reasonable medical basis standard. We also do not agree that deference should be provided to the attesting physician's findings. Accepting claimant's assertion would be inconsistent with this court's decision to impose a 100 percent audit requirement for all claims for Matrix Benefits. See Mem. in Supp. of PTO No. 2662, at 13 (Nov. 16, 2002).

16. Accordingly, there is no basis for claimant's assertion that Dr. Vigilante did not dispute any of the findings of Dr. Dlabal or Dr. Koppes.

matter, the Seventh Amendment specifically states, "The determinations and actions of the Trust on any aspect of a claim for Cash/Medical Services Benefits of a Category One Class Member or Category Two Class Member, or on any claim for the Matrix Election Payment, shall have no preclusive or precedential effect of any kind on the Trust in the administration ... of claims for Seventh Amendment Matrix Compensation Benefits."[17] Seventh Amendment § IX.E. The Seventh Amendment further provides that:

> For each Category One Class Member or Category Two Class Member found to be eligible for Seventh Amendment Matrix Compensation Benefits, the Trust shall calculate as a Net Matrix Amount, a sum equal to the gross amount payable to the Diet Drug Recipient or Representative Claimant and their associated Derivative Claimants, if any, on the applicable Matrix under section IV.B.2 of the Settlement Agreement ....

Id. § IX.A.2. (emphasis added). Section IV.B.1.a. of the Settlement Agreement sets forth:

> 1. .... The following Class Members, and only such Class Members, shall be entitled to the compensation benefits from Fund B ("Matrix Compensation Benefits"):

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17. Under the Seventh Amendment, Seventh Amendment Matrix Compensation Benefits means "those Matrix Compensation Benefits which may be paid or claimed for High Matrix Level Qualifying Factors to or by Category One Class Members or Category Two Class Members in accordance with the terms of the Seventh Amendment." Seventh Amendment § I.64. Ms. Meyer is a Category Two Class Member, and her claim for Level V Matrix Benefits is a claim for Seventh Amendment Matrix Compensation Benefits.

> a. Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive[18] ... by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period ....

As claimant has not established a reasonable medical basis for finding that she had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period, the Settlement Agreement requires that her claim be denied.

Therefore, we will affirm the Trust's denial of Ms. Meyer's claim for Matrix B-1, Level V benefits.

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18. FDA Positive is defined, in pertinent part, as "mild or greater regurgitation of the aortic valve." Settlement Agreement § I.22.a.